

US EPA ARCHIVE DOCUMENT

The following documents are included in the EMD-003 folder:

EMD-003: Laboratory Tick Repellency

- a. Transmittal EMD-003 9/10/06
This document summarizes the changes made to the protocol since the June HSRB meeting
- b. EMD-003 with IRB approval 9/12/06
This includes the protocol itself (dated 9/8/06), the IRB approval letter (9/12/06), and the IRB-approved informed consent document (9/12/06)
- c. EMD-003 Errata 9/14/06
This corrects editorial errors in the protocol
- d. Training Materials for subjects
 - i. Tick Handling Training Materials
 - ii. Dosimetry Training Materials (Same as for EMD-004)
- e. IRB Review of EMD-003
This document contains minutes of the convened IIRB reviews of this protocol both in April 2006 and again in July 2006, as well as all other case-specific documentation provided by the IRB.
- f. IRB Correspondence Record
This is a chronological compilation of all email exchanged between Carroll-Loye Biological Research and IIRB concerning this protocol or EMD-004.
- g. EPA Science & Ethics Review of EMD-003: 9/15/06
This document includes both science and ethics reviews in a single document, supported by an expanded “framework” incorporating the criteria for protocol review recommended by the HSRB, and by explicit assessments of completeness and compliance with regulatory requirements of Subpart K.